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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,296

09/15/2005

Ales Franc

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1964

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

06/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,296	Applicant(s) FRANC ET AL.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/28/09 has been entered.
2. Applicant's arguments filed on 11/4/08 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-19 are pending in this office action.
5. Claims 1-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mckeage et al. (1995) in view of Zak et al., (US 6,503,943) and Collaueri et al., (US 6,221,393) further in view of Keppler et al., (US 5,256,653) and Calanchi et al. (US 5,900,252) as evidence by Swarbrick-Encyclopedia (1998) for the reasons made of record in Paper No. 20090109 and as follow.

Applicant again argues that “when assessing whether a technical solution is or not obvious from the prior art two items should be taken into consideration, the technical problem to be solved and the technical solution by which the inventors solve such technical problem”. Applicant also argues that the cited prior art can be divided into three groups: in summary that document mentioning neither the common wet granulation nor the present excipients (i.e., Zak has no relevance to the rejection since it does not hint on any feature of claim 1, and that the Mckeage, Keppler and Calanchi when considered separately without combining them with further prior art have no relevance to the present solution.

Applicant also argues that the present solution would not have been derived from neither Collaueri and Swarbrick, and that Callaueri focused on hydrophilic xanthan gums having quite different properties than those of the polysaccharide used in the present solution. Additionally and Collaueri does not mention the tetravalent platinum complexes, and wet granulation. Lastly, Applicant argues that the Encyclopedia of Pharmaceutical Technology only provides a general definition of the granulation.

In response with regards to the argument that in assessing whether a technical solution is obvious, the claims are not directed to solving a technical solution but merely to a “pharmaceutical composition” containing platinum complex in a mixture of at least one pharmaceutical acceptable excipient formed of a granulate with particles smaller than 0.5 mm in size. Accordingly, the combination of references are *prima facie* obvious for one of ordinary skill in the art to have used the teachings of the prior art to obtain the claim invention with a reasonable expectation of success.

Applicant again is incorrect that Zak does not contribute to the instant claim 1. Zak was introduced to show that inclusion of excipients to form a platinum complex were known in the prior art before filing of the instant invention, and ties in with the teachings of Mckeage. Zak also is employed for its teaching that the platinum complex is (OC-6-43) Bis (acetato)-(1-adamantylamine)-amine-dichloroplatinum (see col. 3, lines 48-51, as required by instant claim 4). Thus compounds of claims 1 and 4 are obvious variations of instant formula I wherein the complex comprises a native saccharide, cyclodextrin, that may also be modified.

Applicant should note that the rejection was made under 103 and not 102, so obviousness is established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so is found in either the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the combined teachings of the references would have suggested to those of ordinary skill in the art to formulate a "pharmaceutical composition" containing a platinum complex, for the reasons made of record. McKeage specifically teach the formulation in Example I of the specification (when the specification is used as a dictionary) wherein the composition for wet granulation comprises a platinum IV complex (i.e., JM 216), a modified starch (i.e., sodium starch glycolate); microcrystalline cellulose (i.e., a poly saccharide) and lactose, see page 452 under drug). Mckeage is only lacking in the teaching that the formulation is produced by

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wet granulation with particles smaller than 0.5 mm. As further evidenced by Kaplan et al. (US 4,302,446, newly submitted), wet granulation of platinum IV complexes in a 0.5 mm range of particle size is (see col. 5, lines 37-41 and col. 8, lines 32-40).

As to the argument that Collaueri does not teach a platinum complex, this is irrelevant in this 103 rejection, because Collaueri is used to show that granules entering into pharmaceutical compositions are advantageously prepared from a polysaccharide having particles less than 100 μ M, which is less than 0.5 mm, and therefore is alternatively relevant to the formulation, itself.

The statement that different polysaccharides are used in Collaueri is also found not persuasive because the skilled artisan would have been motivated to employ polysaccharides other than xanthum gums in a wet granulation process with a neutral saccharide and a polysaccharide, as claimed in instant claim 2, because no specific type of polysaccharide is required in instant claims 2 and 6 (for example). Applicant should also note that Collaueri teaches the composition is produced or processed by wet granulation, as stated in the last office action of record.

Thus from the evidentiary support, one of ordinary skill in the art would have substituted Mckeage's platinum IV complex with Zak's platinum complex to formulate a tablet by a wet granulation process because wet granulation is used to improve flow, compressibility, bio-availability, and homogeneity of low dose blends, electrostatic properties of powders, and stability of dosage forms. One of ordinary skill in the art would have reasonably expected success in substituting Mckeage's compound JM 216 with Zak's compound ((OC-6-43) Bis(acetato)-(1-adamantylamine)-amine-

dichloroplatinum) because both compounds are used for the same treatment conditions and substituting one for the other is within the purview of the skilled artisan.

6. Claims 12-19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mckeage et al. (1995) in view of Zak et al. (US 6,503,943) and Collaueri et al., (US 6,221,393), further in view of Keppler et al., (US 5,256,653) and Calanchi et al. (US 5,900,252), as evidenced by Swarbrick-Encyclopedia of Pharmaceutical Technology (1998), as applied to **claims 1-11** for the reasons made of record in Paper No. 20090109 and as follow.

The above argument and response also applies here in its entirety.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
1/9/09

/Robert C. Hayes/
Primary Examiner, Art Unit 1649